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|------------------------------|-------------|----------------------|-----------------------|------------------|
| APPLICATION NO.              | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
| 10/070,954                   | 07/22/2002  | Stephen Arkinstall   | ARKINSTALL,1          | 4903             |
| 1444                         | 7590        | 03/10/2010           | EXAMINER              |                  |
| BROWDY AND NEIMARK, P.L.L.C. |             |                      | COLEMAN, BRENDA LIBBY |                  |
| 624 NINTH STREET, NW         |             |                      | ART UNIT              | PAPER NUMBER     |
| SUITE 300                    |             |                      |                       | 1624             |
| WASHINGTON, DC 20001-5303    |             |                      | MAIL DATE             | DELIVERY MODE    |
|                              |             |                      | 03/10/2010            | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**ADVISORY ACTION**

Claims 1, 2, 5-12, 20-22, 27-31 and 35 are pending in the application.

The period for reply continues to run FOUR MONTHS from the date of the final rejection. Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a) accompanied by the appropriate fee. The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. A reply within the meaning of 37 CFR 1.113 or a request for a continued examination (RCE) in compliance with 37 CFR 1.114 must be timely filed to avoid abandonment of this application.

The amendment filed March 3, 2010 under 37 CFR 1.116 in reply to the final rejection has been entered, but is not deemed to place the application in condition for allowance. For purposes of appeal, the status of the claims is as follows:

Allowed claim(s): NONE

Rejected claim(s): 1, 2, 5-12, 20-22, 27-31 and 35

Claim(s) objected to: NONE

This action is in response to applicant's amendment dated March 3, 2010.

Claims 1, 2, 9, 11, 21 and 31 have been amended.

***Response to Arguments***

Applicant's arguments filed March 3, 2010 have been fully considered with the following effect:

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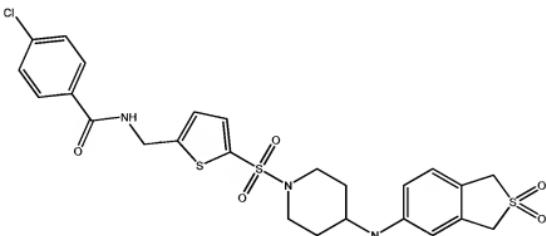
1. The applicants' amendments are sufficient to overcome the provisional obviousness-type double patenting rejection of claims 1-3 and 5-41 labeled paragraph 1) over copending Application No. 10/381,200 maintained in the last office action, which is hereby **withdrawn**.

2. With regards to the provisional obviousness-type double patenting rejection of claims 1, 2, 5-12, 20-22, 27-31 and 35 labeled paragraph 2) over copending Application No. 10/381,665 maintained in the last office action, the applicants requested that this rejection be held in abeyance at this time. However, in light of the allowance of Application No. 10/381,665 the rejection is no longer a provisional double patenting rejection.

Claims 1, 2, 5-12, 20-22, 27-31 and 35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 12-14 and 17-21 of U.S. Patent No. 7,544,700, for reason of record and stated above.

3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections, labeled paragraph 3b), o), p), v), y), cc), gg and kk) maintained in the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections, labeled paragraph 3g), h), l), t), u), x), bb), hh), ii) and nn) maintained in the last office the applicant's amendments and arguments have been fully considered, however they were not found persuasive.

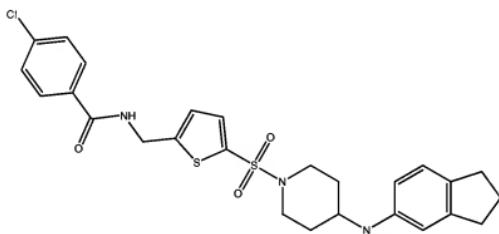
g) The applicants' stated that the definiteness of claim language is analyzed, not in a vacuum, but in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art and that it is a well-established axiom in patent law that a patentee or applicant is free to be his or her own lexicographer so long as the terminology used is clearly defined in the specification. The applicant points to page 5, lines 21 to page 6, line 2 of the international application, where a heteroaryl group can be a bicyclic fused heteroaromatic ring. Moreover, the group benzothienyl, on which the L substituent of this species is based, is explicitly mentioned on page 5, line 25. However, the definition of the substituents on the piperidinyl moiety of Y does not include the substituents as claimed herein. Claim 11 recites the limitation "**2,2-dioxido-1,3-dihydro-2-benzothien-5-yl**" in the 8<sup>th</sup> species on page 17. The substituent is not benzothienyl, but 1,3-dihydro-2-benzothienyl and is therefore not a heteroaromatic but a heterocyclic.



4-chloro-N-{[5-({4-[{2,2-dioxido-1,3-dihydro-2-benzothien-5-yl}amino]piperidin-1-yl}sulfonyl)thien-2-yl][methyl]benzamide

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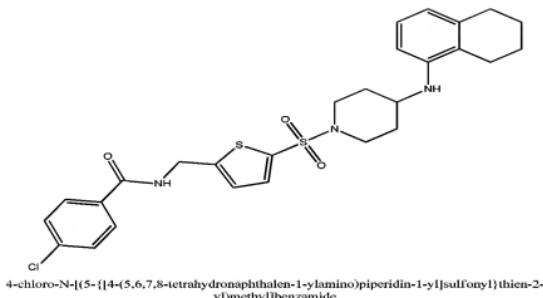
h) The applicants' stated that R<sup>3</sup> and R<sup>3'</sup> can be aryl groups and according to the definition provided on page 5, line 16 of the international application, an aryl group can be an aromatic carbocyclic group of from 6 to 14 carbon atoms. The group dihydroindenyl is a fused bicyclic aromatic system and is therefore clearly embraced by the definition of an aryl group. However, the dihydroindenyl is not aromatic but a carbocyclic ring system, thus the species of Claim 11 where the claim recites the limitation "2,3-dihydro-1H-inden-5-yl" in the 9<sup>th</sup> species on page 17 lacks antecedent basis.



4-chloro-N-[(5-[(4-(2,3-dihydro-1H-inden-5-ylamino)piperidin-1-yl)sulfonyl]thien-2-yl)methyl]benzamide

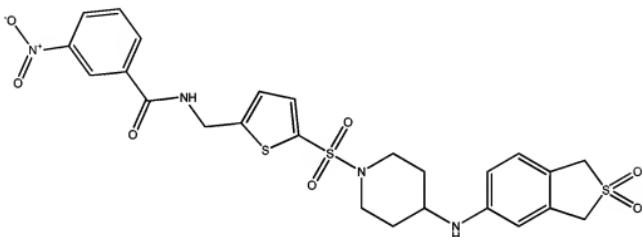
I) The applicants' stated that R<sup>3</sup> and R<sup>3'</sup> can be aryl groups and according to the definition provided on page 5, line 16 of the international application, an aryl group can be an aromatic carbocyclic group of from 6 to 14 carbon atoms. The group tetrahydronaphthalen is a fused bicyclic aromatic system and is therefore clearly embraced by the definition of an aryl group. However, the tetrahydronaphthalen is not aromatic but a carbocyclic ring system, thus the species of Claim 11 where the claim recites the limitation "4-(5,6,7,8-tetrahydronaphthalen-1-ylamino)" in the 5<sup>th</sup> species on page 18 lacks antecedent

basis.



- t) The applicants' stated that the definiteness of claim language is analyzed, not in a vacuum, but in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art and that it is a well-established axiom in patent law that a patentee or applicant is free to be his or her own lexicographer so long as the terminology used is clearly defined in the specification. The applicant points to page 5, lines 21 to page 6, line 2 of the international application, where a heteroaryl group can be a bicyclic fused heteroaromatic ring. Moreover, the group benzothienyl, on which the L substituent of this species is based, is explicitly mentioned on page 5, line 25. However, the definition of the substituents on the piperidinyl moiety of Y does not include the substituents as claimed herein. Claim 11 recites the limitation "2,2-dioxido-1,3-1,3-dihydro-2-benzothien-5-yl" in the 1<sup>st</sup> species on page 22. The substituent is not

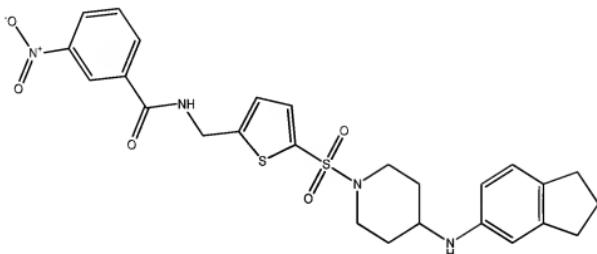
benzothienyl, but 1,3-dihydro-2-benzothienyl and is therefore not a heteroaromatic but a heterocyclic.



N-[{5-[(4-[(2,2-dioxido-1,3-dihydro-2-benzothien-5-yl)amino]piperidin-1-yl)sulfonyl]thien-2-yl}methyl]-3-nitrobenzamide

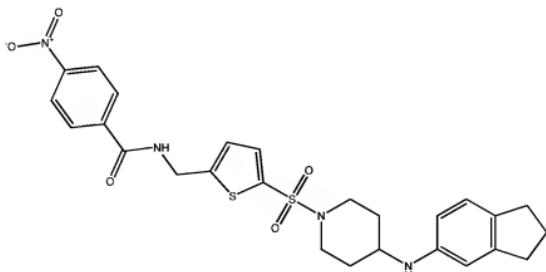
- u) The applicants' stated that R<sup>3</sup> and R<sup>3a</sup> can be aryl groups and according to the definition provided on page 5, line 16 of the international application, an aryl group can be an aromatic carbocyclic group of from 6 to 14 carbon atoms. The group dihydroindenyl is a fused bicyclic aromatic system and is therefore clearly embraced by the definition of an aryl group. However, the dihydroindenyl is not aromatic but a carbocyclic ring system, thus the species of Claim 11 where the claim recites the limitation "2,3-dihydro-1H-inden-5-yl" in the 2<sup>nd</sup> species on page 22 lacks antecedent basis.

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N-[{5-[(4-(2,3-dihydro-1H-inden-5-ylamino)piperidin-1-yl]sulfonyl}thien-2-yl)methyl]-3-nitrobenzamide

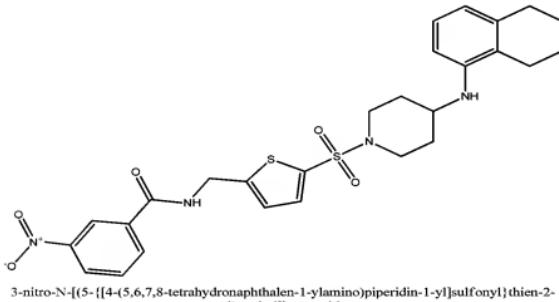
x) The applicants' stated that R<sup>3</sup> and R<sup>3'</sup> can be aryl groups and according to the definition provided on page 5, line 16 of the international application, an aryl group can be an aromatic carbocyclic group of from 6 to 14 carbon atoms. The group dihydroindenyl is a fused bicyclic aromatic system and is therefore clearly embraced by the definition of an aryl group. However, the dihydroindenyl is not aromatic but a carbocyclic ring system, thus the species of Claim 11 where the claim recites the limitation "2,3-dihydro-1H-inden-5-yl" in the 10<sup>th</sup> species on page 22 lacks antecedent basis.



N-[{5-[(4-(2,3-dihydro-1H-inden-5-ylamino)piperidin-1-yl]sulfonyl}thien-2-yl)methyl]-4-nitrobenzamide

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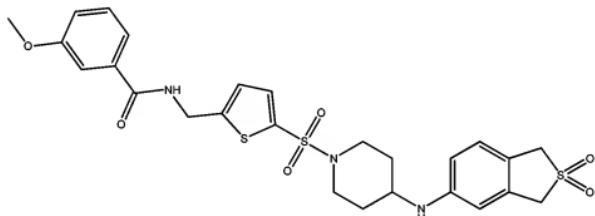
bb) The applicants' stated that R<sup>3</sup> and R<sup>3'</sup> can be aryl groups and according to the definition provided on page 5, line 16 of the international application, an aryl group can be an aromatic carbocyclic group of from 6 to 14 carbon atoms. The group tetrahydronaphthalen is a fused bicyclic aromatic system and is therefore clearly embraced by the definition of an aryl group. However, the tetrahydronaphthalen is not aromatic but a carbocyclic ring system, thus the species of Claim 11 where the claim recites the limitation "4-(5,6,7,8-tetrahydronaphthalen-1-yl)" in the 10<sup>th</sup> species on page 23 lacks antecedent basis.



hh) The applicants' stated that the definiteness of claim language is analyzed, not in a vacuum, but in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art and that it is a well-established axiom in patent law that a patentee or applicant is free to be his or her own lexicographer so long as the terminology used is clearly defined in the specification. The applicant

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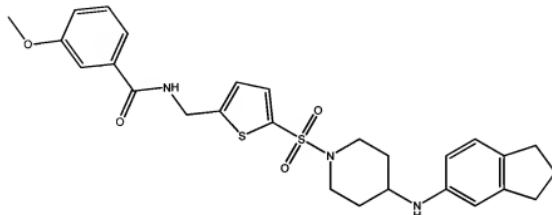
points to page 5, lines 21 to page 6, line 2 of the international application, where a heteroaryl group can be a bicyclic fused heteroaromatic ring. Moreover, the group benzothienyl, on which the L substituent of this species is based, is explicitly mentioned on page 5, line 25. However, the definition of the substituents on the piperidinyl moiety of Y does not include the substituents as claimed herein. Claim 11 recites the limitation "2,2-dioxido-1,3-dihydro-2-benzothien-5-yl" in the 8<sup>th</sup> species on page 26. The substituent is not benzothienyl, but 1,3-dihydro-2-benzothienyl and is therefore not a heteroaromatic but a heterocyclic.



N-{{[5-{[(4-[(2,2-dioxido-1,3-dihydro-2-benzothien-5-yl)amino]piperidin-1-yl)sulfonyl]thien-2-yl]methyl}-3-methoxybenzamide}

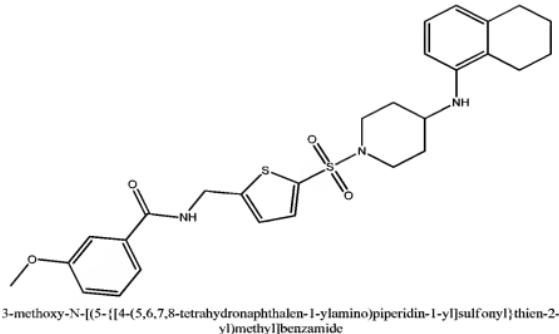
ii) The applicants' stated that R<sup>3</sup> and R<sup>3'</sup> can be aryl groups and according to the definition provided on page 5, line 16 of the international application, an aryl group can be an aromatic carbocyclic group of from 6 to 14 carbon atoms. The group dihydroindenyl is a fused bicyclic aromatic system and is therefore clearly embraced by the definition of an aryl group. However, the dihydroindenyl is not aromatic but a carbocyclic ring system, thus the species of Claim 11 where the

claim recites the limitation "2,3-dihydro-1H-inden-5-yl" in the 9<sup>th</sup> species on page 26 lacks antecedent basis.



N-((5-((4-(2,3-dihydro-1H-inden-5-ylamino)piperidin-1-yl)sulfonyl)thien-2-yl)methyl)-3-methoxybenzamide

nn) The applicants' stated that R<sup>3</sup> and R<sup>3'</sup> can be aryl groups and according to the definition provided on page 5, line 16 of the international application, an aryl group can be an aromatic carbocyclic group of from 6 to 14 carbon atoms. The group tetrahydronaphthalen is a fused bicyclic aromatic system and is therefore clearly embraced by the definition of an aryl group. However, the tetrahydronaphthalen is not aromatic but a carbocyclic ring system, thus the species of Claim 11 where the claim recites the limitation "4-(5,6,7,8-tetrahydronaphthalen-1-yl)" in the 4<sup>th</sup> species on page 27 lacks antecedent basis.



4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection, labeled paragraph 7) of the last office action, which is hereby **withdrawn**.
  
5. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections, labeled paragraph 8a), b), c), e), f), g), h), i), l), m), n), o), p) and q) in the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections, labeled paragraph 8d), j) and k) in the last office the applicant's amendments and arguments have been fully considered, however they were not found persuasive.

- d) The applicants' stated that they have removed the second proviso from claim 1 and the first proviso from claim 2 as not being under the scope of the compounds of Formula (I). However, the second proviso in claim 2 has not been removed.

Claim 2 recites the limitation "β position" in the second proviso. There is insufficient antecedent basis for this limitation in the claim.

j) The applicants' failed to comment on the rejection labeled paragraph 8j) which is herein maintained.

Claim 11 recites the limitation "hydroxy" in the definition of L<sup>1</sup> and L<sup>2</sup>. There is insufficient antecedent basis for this limitation in the claim. See the 5<sup>th</sup> species on page 12.

k) The applicants' failed to comment on the rejection labeled paragraph 8j) which is herein maintained.

Claim 11 recites the limitation "4-(5-thien-2-yl-1H-pyrazol-3-yl)" in the definition of L<sup>1</sup> and L<sup>2</sup>. There is insufficient antecedent basis for this limitation in the claim. See the 4<sup>th</sup> species on page 13.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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/Brenda L. Coleman/  
Primary Examiner, Art Unit 1624